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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,703	07/20/2001	Bruce J. Barclay	VASC 1020-2	2083

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EXAMINER
PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 08/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/910,703	BARCLAY ET AL.	
	Examiner	Art Unit	
	Brian E Pellegrino	3738	

-- *The MAILING DATE of this communication appears on the cover sheet with th correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2003 and 06 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,4,8,9,11,19-23,25,26,38-43,45-57,59-62,74-78 and 101-110* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,4,8,9,11,19-23,25,26,38-43,45-57,59-62,74-78 and 101-110* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

Applicant's request for reconsideration and review of the Supplemental amendment submitted 5/22/03 is persuasive and, therefore, the finality of that action is withdrawn. The "After Final amendment" has been entered and an Office Action on the merits follows.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "the sleeve interior is oversized relative to the coiled body so to loosely contain the coiled body."

Claim Objections

Claim 108 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim depends from a canceled claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 105,107,109,110 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is noted that on page 13, lines 1,2,7-10 that NO generators are disclosed, but the disclosure fails to describe how or where NO is generated.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3,9,26,38-41,74-77,101-104 are rejected under 35 U.S.C. 102(b) as being anticipated by Razavi (5676685). Figs. 11 and 13 show a coiled body **12** with radially extending openings between the adjacent rings. Claims in a pending application are given their broadest reasonable interpretation, In re Hyatt, 211 F.3d 54 USPQ2d 1664 (Fed. Cir. 2000). In this instance it can be construed that the material **14** extending along the coiled path there is a material forming a coiled sleeve. Since this material **14** "encases" the coiled body **12** it is a sleeve, see Fig. 2 showing that the coil **12** is surrounded by material **14** and can be considered to loosely contain the coil body. Razavi discloses that an anti-thrombotic drug is associated with the material, col. 3, lines 22-25. Fig. 2 shows that a delay-release material or biodegradable layer **16** is used on the material with the drug, col. 3, lines 12-17. Razavi also discloses the body or core coil is made of metal, col. 2, lines 37-47. Razavi additionally discloses a sheath

or sleeve can be the protective layer and pulled off upon deployment, col. 6, lines 13-16. Regarding claims 41,45,77, Figs. 8 and 10 show the prosthesis with spaced apart turns defining gaps in the radially expanded state. Fig. 1 shows the sleeve following the coil body and thus has regions occupied by the coiled body and open spaces not occupied by the coiled body since it is shown as being oversized with the coil in the center of the sleeve. Razavi discloses that the stent is delivered inside a vessel of a patient, col. 2, lines 15-17. The agent is inherently capable of being dispensable from the sleeve interior through the inner surface and out the outer surface of the sleeve material.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4,8,19-23,25,38,42,101,102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zukowski et al. (WO 97/40755) in view of Kropf (4760849) and Ragheb et al. (5873904). Zukowski et al. disclose (Figs. 15,16) a stent having a coiled body **501** with a porous graft material extending along and completely covering the coiled body. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure. Clearly, the support device is capable of being used for inside a blood vessel. Zukowski also discloses the stent body is made of metal, page 9, col. lines 25,26. Zukowski additionally discloses the graft material is ePTFE and can also have a protective layer, page 9, lines 23,24,34,35. Regarding claims 25, 54, it is inherent that the inner surface of the porous material is impervious to blood such that the blood vessel does not leak from the prosthetic device being applied

thereto. However, Zukowski et al. do not disclose a stent body that has spaced-apart parallel side elements joined by connector elements or an agent in the porous graft material or that the outer covering is biodegradable. Kropf teaches a stent body with spaced-apart parallel side elements joined by connector elements, Fig. 5. Ragheb teaches a drug layer with a porous covering thereon, col. 4, lines 23-32. Ragheb also teaches the drugs that can be delivered via the stent include anti-inflammatories and antiproliferatives or antirestenotic agents, col. 4, lines 60-67. Ragheb additionally teaches the bioactive material or drugs can be microencapsulated, col. 19, lines 60-63. Ragheb teaches the outer porous layer can be a polymer that is biodegradable, col. 13, lines 33-44. Ragheb also teaches the use of first and second dispensable agents, col. 5, lines 58,59,63 and col. 6, lines 3-14. It would have been obvious to one of ordinary skill in the art to substitute the stent design of Kropf in the device of Zukowski et al. in order to provide a stent with greater structural support and to incorporate a drug such as an anti-inflammatory in the polymer as taught by Ragheb with the stent graft of Zukowski as modified by Kropf in order to locally administer a drug to be absorbed into the vessel through the wall of the vessel.

Regarding claim 22, it would have been an obvious matter of design choice to modify the ability of the stent to release at least half of a first agent before a second is released, since applicant has not disclosed that using any set amount of one over another provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the rates and amounts taught by

Ragheb or the claimed at least half of first agent in claim(s) 22 because both designs perform the same function of releasing agents into the patient.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Razavi '685 in view of McNamara et al. (5147370). Razavi is explained supra. However, Razavi does not disclose the prosthesis comprising turns touching one another when in the expanded state. McNamara et al. show a coil (Fig. 1) with turns touching one another when in the expanded state, see also col. 3, lines 55,56. McNamara also teaches the coil is to be designed with closely spaced turns, col. 6, lines 19-23. It would have been obvious to one of ordinary skill in the art to use a closely spaced turned coil as taught by McNamara with the coiled body of Razavi in order to provide more structural support to the vessel.

Claims 43,47,52-58,61,62,106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosen et al. (5797887) in view Kropf '849. Rosen et al. disclose a method of delivering an agent inside a blood vessel, such as a NO generator using a stent, col.6, lines 24-33. Rosen also discloses biodegradable polymers can be used to control rates of delivery of NO, col. 7, lines 33-45. Rosen additionally discloses porous PTFE can be used on the stent, which is substantially impervious to blood, col. 8,lines 43-52. However, Rosen et al. fail to disclose a coiled stent with radial openings and side members connecting longitudinal members. Kropf is explained supra. Kropf teaches that the structural design enables the prosthesis to be deployed in a small profile reducing the likelihood of vessel trauma, col. 3, lines 8-13. It would have been obvious to one of ordinary skill in the art to substitute the stent design of Kropf in the device of

Rosen et al. in order to provide a stent with good flexibility and a small profile for delivery. By incorporating the coil body in the stent of Rosen, the prosthesis will inherently have a coiled sleeve because Rosen discloses coating the device.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosen et al '887 in view of Kropf '849 as applied to claim 43 above, and further in view of McNamara et al. '370. Rosen as modified by Kropf is explained supra. However, Rosen in view of Kropf do not disclose the prosthesis comprising turns touching one another when in the expanded state. McNamara et al. show a coil (Fig. 1) with turns touching one another when in the expanded state, see also col. 3, lines 55,56. McNamara also teaches the coil is to be designed with closely spaced turns, col. 6, lines 19-23. It would have been obvious to one of ordinary skill in the art to use a closely spaced turned coil as taught by McNamara with the coiled body of Rosen as modified by Kropf in order to provide more structural support to the vessel.

Claims 48-51,60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosen et al '887 in view of Kropf '849 as applied to claim 43 above, and further in view of Ragheb et al. '904. Rosen in view of Kropf is explained supra. However, Rosen as modified by Kropf do not disclose the use of two agents or the rates of use of them. Ragheb is explained supra. Ragheb also teaches that a protective or outer layer is placed on the bioactive layer to protect the base material of the device from the blood, col. 12, lines 38-56. It would have been obvious to one of ordinary skill in the art to incorporate a second agent and also use a protective outer layer as taught by Ragheb with the stent of Rosen et al. as modified by Kropf in order to locally administer multiple

drugs within the vasculature to reduce restenosis and trauma effects in the patient vessel, while also maintaining the integrity of the device and protecting the patient from any absorption of noncompatible materials. With respect to claim 51, it would have been an obvious matter of design choice to modify the ability of the stent to release at least half of a first agent before a second is released, since applicant has not disclosed that using any set amount of one over another provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the rates and amounts taught by Ragheb or the claimed at least half of first agent in claim(s) 51 because both designs perform the same function of releasing agents into the patient.

Claim 78 is rejected under 35 U.S.C. 103(a) as being unpatentable over Razavi '685 in view Ragheb et al. '904. Razavi is explained supra. However, Razavi does not disclose the polymer as PTFE. Ragheb teaches that porous polymers, such as PTFE can be placed on the stent (col. 5, lines 43,44,50) and is used for controlling drug release, col. 6, lines 56-60. It would have been obvious to one of ordinary skill in the art to substitute PTFE as taught by Ragheb for the polymer material of Razavi in order to control release rates of therapeutic material administered to the patient.

Claims 105,107,109,110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Razavi in view of Hanson '352. Razavi is explained as before. However, Razavi does not disclose the use of a NO generator as the agent. Hanson teaches that NO generators are used to prevent or treat restenosis, col. 6, lines 3-5,60-

64. It would have been obvious to one of ordinary skill in the art to use a NO generator as taught by Hanson with the stent of Razavi having a bioactive agent such the NO generator prevents restenosis in the patient while the stent is in the body. NO is capable of being generated since the material can be impregnated in the sleeve of Razavi.

Response to Arguments

Applicant's arguments filed 4/17/03 have been fully considered but they are not persuasive. In response to the remarks regarding the Razavi reference, it is noted that Fig. 2 shows that material does encase the coil and thus it can be characterized as a sleeve. Since this structure of Razavi is equivalent to Applicant's embodiment presented in Fig. 5, it must anticipate the claims. Since the Razavi stent is designed analogous to Applicant's, it inherently comprises open spaces not occupied by the coiled body.

With respect to the comments about the McNamara reference and that it teaches away from the invention as claimed. First it must be noted that structurally, McNamara teaches the claimed limitation and secondly there is no recitation in the claim that the turns touching one another promote tissue ingrowth.

Regarding Applicant's remarks that porous material of Zukowski is not impervious to blood, it must be noted that the material is the same as what is claimed and thus possesses the same properties as the claimed material.

Applicant's arguments with respect to claim 43 have been considered but are moot in view of the new ground(s) of rejection.

C nclusion

Applicant's AF amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 8am to 5:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino

TC 3700, AU 3738
August 19, 2003

Bruce Snow

Primary Examiner